

REMARKS

Claims 41-75 were pending. By virtue of this response, claims 56, 65, and 68 are amended, and claims 41, 52, 55, 66, 70, 72 and 74 are canceled. Claims 42-51, 53, 54, 57-64, 67, 69, 71, 73, and 75 are withdrawn. Therefore, claims 56, 65, and 68 are presently pending for examination. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter is added.

I. Claim Objections

Claim 74 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicants have canceled claim 74 and therefore request that this objection be withdrawn.

II. Claim Rejections Under 35 USC §112

Claims 41, 52, 65, 66, 68, 70, 72 and 74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for the delivery of gaseous nitric oxide (NO), comprising specific compounds bonded to NO, wherein said compound is a water miscible organic compound, comprising at least one hydroxyl group, does not reasonably provide enablement for a similar composition comprising any compounds bonded to NO, wherein said compound is a water miscible organic compound, comprising at least one hydroxyl group.

Claims 41, 52, 66, 70, 72, and 74 have been canceled, rendering the rejection moot as to those claims.

The pending rejected claims, 65 and 68, have been amended to depend from claim 56. Claim 56 is directed to “[a] composition for the delivery of gaseous nitric oxide (NO), comprising a compound bonded to NO, wherein said composition contains substantially no oxygen, **wherein said compound is 1, 2-propanediol or 1, 3-propanediol.**” (Emphasis added).

Applicants respectfully assert that, as amended, claims 65 and 68 are enabled, as a person of skill in the art would be able to make and/or use the invention without undue experimentation, based on the present specification. Applicants further note that claim 56, from which the rejected claims now depend, was not rejected for lack of enablement.

Applicants respectfully request that this basis of rejection be withdrawn.

III. Claim Rejections Under 35 USC §102

Godin

Claims 41, 52, 55, 56, 66 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by journal publication to Steven Godin et al. (PTO-892, Ref. U) (hereinafter “Godin”).

Claims 41, 52, 55, and 56 have been canceled, rendering the rejection moot as to those claims.

Remaining rejected claims 56 and 68 are now directed to compositions “comprising a compound bonded to NO, wherein said composition contains substantially no oxygen, wherein said compound is 1, 2-propanediol or 1, 3-propanediol.” As recognized by the Examiner on page 15 of the Final Office Action, Godin does not disclose that the composition comprising PGDN is substantially free of oxygen. As such, Godin fails to teach every element of the claim.

Applicants request that the 35 U.S.C. 102(b) rejection over Godin be withdrawn.

Fung

Claims 41, 52, 55, 56, 65, 66 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,646,181 to Fung et al. (hereinafter referred to as the “Fung”).

Claims 41, 52, 55, and 66 have been canceled, rendering the rejection moot as to those claims.

Remaining rejected claims 56 and 68 are now directed to compositions “comprising a compound bonded to NO, wherein said composition contains substantially no oxygen, wherein said compound is 1, 2-propanediol or 1, 3-propanediol.” As recognized by the Examiner on page 16 of the Final Office Action, Fung does not disclose that its compositions are substantially free of oxygen. As such, Fung fails to teach every element of the claim.

Applicants request that the 35 U.S.C. 102(b) rejection over Fung be withdrawn.

IV. Claim Rejections Under 35 USC §103

Godin in view of Fung

Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable Godin view of Fung.

Claim 65 has been amended to depend from claim 56. As amended, claim 65 requires that the composition be “substantially free of oxygen.” Neither Godin nor Fung disclose use of compositions for the delivery of (NO) that are “substantially free of oxygen.” As such, it would not have been obvious to modify Godin or Fung to arrive at a composition for the delivery of (NO) that is “substantially free of oxygen.”

Applicants request that the rejection under 35 U.S.C. 103(a) over Godin view of Fung be withdrawn.

Godin in view of Lindberg

Claims 70, 72¹, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godin in view of the journal publication by Lindberg et al. (PTO-892, Ref. V) (hereinafter “Lindberg”).

Claims 70, 72, and 74 have been canceled, rendering the rejection moot as to those claims. Applicants hereby address the substance of the rejection, with respect to pending claims 56, 65, and

68, which contain the “substantially free of oxygen” limitation presented in canceled claims 70, 72, and 74.

As discussed above, Godin does not teach a composition for the delivery of (NO) that is “substantially free of oxygen.” Lindberg does teach that the main problem during inhalation of nitric oxide is its reactivity with oxygen to form the highly toxic nitrogen dioxide.

However, because of the unpredictability of the pharmaceutical art, it is not *prima facie* obvious to one of ordinary skill in the art to apply the teaching of Lindberg to non-gaseous compositions for the delivery of NO. A person of skill would not, based on the teaching of Lindberg, consider the formation of nitrogen dioxide to be an issue in a non-gaseous composition and would therefore have no rationale for modifying the composition of Godin to be “substantially free of oxygen.”

Applicants request that the rejection under 35 U.S.C. 103(a) over Godin view of Lindberg be withdrawn.

Fung in view of Lindberg

Claims 70, 72², and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fung in view of Lindberg.

For the reasons stated above with respect to Godin in view of Lindberg, Applicants submit that one of ordinary skill in the art would not derive from Lindberg a rationale for modifying the composition of Fung to be “substantially free of oxygen.”

Applicants request that the rejection under 35 U.S.C. 103(a) over Fung view of Lindberg be withdrawn.

¹ The Office Action appears to contain a typographical error resulting in the erroneous rejection of claim 74, twice. Applicants presume that the Examiner intended to also reject claim 72.

² Applicants presume that the Examiner intended to also reject claim 72.

V. Double Patenting

Claims 41, 52, 55, 56, 66, 68, 70, 72 and 74 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29, 32-36 and 38-49 of copending U.S. application no. 12/282,878.

Applicants note that the present application, of the two, is the earlier filed application. If the Examiner finds that this rejection is the only remaining rejection, in view of Applicants' remarks, Applicants request that this rejection be withdrawn in accordance with MPEP 804(I)(B)(2). Applicants reserve the right to substantively traverse this provisional rejection, either in the present application or in U.S. application no. 12/282,878.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 514862003100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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